NORTH DAKOTA
DEPARTMENT OF HEALTH

Division of Air Quality

RADIOACTIVE MATERIAL LICENSING GUIDE

Laboratory Use of Small Quantities
of Radioactive Material

Revised February 2, 2006

CONTENTS

I. INTRODUCTION

This guide outlines the type of information that is needed to evaluate an application for a specific license for laboratories using small quantities of radioactive material. The amount of radioactive material is limited to that allowed under a "Type C specific license of broad scope" as defined in Paragraph 3 of Subdivision a of Subsection 4 of Section 33-10-03-05 of the North Dakota Radiological Health Rules. Licenses for radioactive material are issued pursuant to the North Dakota Radiological Health Rules.

All information submitted as part of this application will be subject to North Dakota's Open Record Statute, Section 44-04-18, "Access to Public Records - Penalty" of the North Dakota Century Code. The information will be available to the public unless confidentiality is granted by the Department. Requests for confidentiality must be submitted in accordance with Section 23-20.1-09.1, "Confidentiality of Records" of the North Dakota Century Code. Confidentiality requests will be considered in accordance with the above-mentioned statutes.

II. FILING AN APPLICATION

Information submitted should pertain to the specific activities for which authorization is sought and should be as complete and detailed as possible. Submission of incomplete information will result in delays because of the correspondence necessary to obtain supplemental information. The information must be sufficient to allow the Department to determine that the proposed equipment, facilities, procedures and controls are adequate to protect health and minimize danger to life and property. Applications should be mailed to:

North Dakota State Department of Health
Division of Air Quality
Radiation Control Program
918 East Divide Ave., 2nd Floor
Bismarck, ND 58501-1947
Phone: 701-328-5188
Fax: 701-328-5185

Since licensees are required to comply with Department rules, license conditions, and the content of submitted applications, at least one copy of all information submitted to the Department should be kept by the applicant for reference.

III. RADIOACTIVE MATERIAL LICENSE APPLICATION FORM

Two copies of the application form should be completed following the instructions provided in this licensing guide and on the application form. One copy should be filed and one kept by the applicant. Since the space provided on the form is limited, additional sheets should be appended as necessary. Supplemental information should be labeled to identify the applicant and reference the item for which

information is being given. The following comments deal with the indicated items:

Item 1: Applicant and Locations of Use: The applicant, corporation or other legal entity should be specified by name and mailing address in item 1(a). Individuals should be designated as the applicant only if they are acting in a private capacity and the use of radioactive material is not connected with their employment with a corporation or other legal entity.

Specify the street address of each location of use. If use is to be at more than one location, the specific addresses shall be specified and a description of the extent of use at each location and a description of the facilities and equipment at each location must be submitted. A post office box is not an appropriate place of use.

Item 4: Personnel: Specify the names of the persons who will supervise the use of radioactive material or who will use radioactive material without supervision.

Item 5: Radiation Safety Officer: Specify the name of the person who will be designated as the radiation safety officer. This person should be responsible for implementing the radiation safety program, and therefore, must be readily available to the users in case of difficulty. This person shall be experienced in radiation protection and in the use and handling of radioactive materials. A detailed description of the radiation safety officer are provided. Typical duties of the radiation safety officer might be:

1. Verification of all purchases of radioactive materials for compliance with possession limits of the license.
2. Periodic review of records such as personnel exposure records, logs of source and material usage, quarterly inventories, survey records, survey instrument calibration records, leak test records, and waste disposal records to assure management that the terms and conditions of the license and applicable rules are being met.
3. Supervision of all users to ensure that personnel monitoring equipment is being worn.
4. Supervision of leak testing of sealed sources and instrument calibrations.
5. Supervision to ensure that licensed material is properly secured against unauthorized removal at all times.
6. Development of operating and emergency procedures and assistance in personnel training and orientation.
7. Providing advice and help for accidents and emergencies.
8. Maintenance of supplies such as radiation safety instruments, radiation signs, labels, and warning tape, forms, and dosimeters.
9. Conducting internal radiation safety audits of licensed activities periodically to assure compliance with the rules and license conditions.

Item 6: Materials: Identify the requested radioactive material by isotope, chemical and physical form, and activity in millicuries or microcuries. A separate possession limit for each nuclide should be specified. Possession limits requested shall cover

the total anticipated inventory, including stored materials and waste. The requested possession limits must be commensurate with the applicant's needs and facilities for safe handling.

If the use of sealed sources and/or plated sources is contemplated, the isotope, manufacturer and model number of each sealed or plated source shall be specified. If a source will be used in a gas chromatograph, gauge, or other device, the manufacturer and model number of the device must be specified.

Item 7: Use: The use to be made of the radioactive materials should be clearly described. Sufficient detail must be given to allow a determination of the potential for exposure to radiation and radioactive materials of both those working with the materials and the public.

Items 8 & 9: Qualifications of Personnel: A resume of the training and experience of each person who will directly supervise the use of material, who will use material without supervision, or who will have responsibilities for radiological safety shall be submitted. The resume shall include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use. The qualifications, training, and experience of each person must be commensurate with the material and its use as proposed in the application. The amount and type of training and experience with radiation and radioactive material required to support a determination of adequacy by the Department will vary markedly with certain factors.

Training shall cover a) principles and practices of radiation protection, b) radioactivity measurements, standardization, and monitoring techniques and instruments, c) mathematics and calculations basic to the use and measurement of radioactivity, and d) biological effects of radioactive materials.

If other persons such as technical assistants and laboratory workers will use radioactive materials in the absence of persons specified above, the specification of the training of such personnel should include a) instruction in radiation safety including topics covered and by whom taught, b) on-the-job training in use of radioactive materials, and c) determination of competency to work without the presence of supervisory personnel.

The use of very small quantities of a few nonvolatile radioactive materials with activities in the microcurie range, under precisely specified and carefully controlled conditions subject to the surveillance of a competent and adequately trained radiation safety officer by a person with a minimum of training and experience may be justified. Such training and experience may consist of a few hours of training and experience in the use of one or more radioactive materials similar to the use proposed in the application under the supervision and tutorship of a licensed user.

The use of small quantities of a number of radionuclides with activities in the millicurie range for general laboratory tracer work under unspecified conditions

requires more extensive training and experience and, depending on the exact nature of the proposed program of use of radionuclides, may require the completion of formal course work at the college or university level covering the areas listed under Item 8 on the application form.

If the use of larger quantities of material (approaching a curie) normally done under carefully controlled conditions using specialized equipment where a potential exists for significant loss and ingestion, inhalation or absorption of the radioactive material by those working with the material, an individual who is to independently use radioactive materials should have a background of formal training in all areas of Item 8 on the application form. The individual must also have extensive experience in work with radioactive material and a thorough working knowledge of the equipment required to safely handle the material.

Also, it may be possible to justify the use of large quantities of radioactive materials in potentially hazardous chemical and physical forms by limiting the potential hazards through the use of enclosed, shielded, functionally effective and carefully maintained special handling equipment operated in accordance with detailed written operating procedures.

Items 10 & 11: Radiation Detection Instruments: Specify the manufacturer's name and model number, the number available, the type of radiation detected (alpha, beta or gamma), the sensitivity range (milliroentgens per hour or counts per minute), the window thickness (milligrams/centimeter^2) and type of use for each radiation detection instrument. The type of use would normally be monitoring, surveying, assaying, or measuring.

Describe your instrument calibration procedure. State the frequency and describe the methods and procedures for calibration of survey and monitoring instruments and systems used in your radiation protection program, such as measuring instruments used to assay sealed source leak tests samples, contamination samples (air samples, surface "wipe" samples, etc.), and bioassay samples. An adequate calibration of survey instruments usually can not be performed with built-in "check sources." Electronic "calibrations" that do not involve a source of radiation are also not adequate to determine the proper functioning and response of all components of an instrument. Daily or other frequent checks of survey instruments must be supplemented every six months with a two-point calibration on each scale of each instrument with the two points located approximately one-third and two-thirds of full-scale for linear scale instruments; of midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments. Survey instruments shall also be calibrated following repair. A survey instrument may be considered properly calibrated when the instrument readings were within $\pm$ 10% of the calculated or known values for each point checked. Readings within $\pm$ 20% are acceptable if a calibration chart or graph is prepared and attached to the instrument. The description must include:

A. Reference standard source to be used,

B. A copy of written calibration procedures and associated radiation safety instructions, and

C. Pertinent experience of each individual who will perform the calibrations.

If the applicant intends to contract out the calibration of instruments, the name, address and license number of the firm should be specified together with the frequency of calibration.

Item 12: Personnel Monitoring and Bioassays: Personnel monitoring is required if a person is likely to receive, in a calendar quarter, 25% of the applicable values specified in Rule 33-10-04-02.1. Personnel monitoring is also required if a person enters a high radiation area (greater than 100 millirem per hour). If personnel monitoring equipment will be used, the name of the organization furnishing the service (film badge, TLD badge, or dosimeters) and the frequency for changing personnel monitors must be specified. If pocket chambers or pocket dosimeters are used, the range of the device in milliroentgens, frequency of reading, and the procedures for maintaining and determining the accuracy of the devices shall be specified.

If personnel monitoring is not used, a calculation or documentation from radiation surveys which demonstrates that it is unlikely that an individual shall receive a dose as indicated above, should be submitted.

Bioassays are normally required when individuals work with multimillicurie quantities or hydrogen-3, iodine-125 or iodine-131, depending on the chemical and physical form, the procedures followed and the equipment used. Acceptable bioassay methods for iodine and tritium consist of the measurement of activity in the thyroid and urine (urinalysis), respectively. Bioassays may also be required for other radionuclides if the chemical or physical form or procedures and equipment used make it possible for radioactive materials to be ingested, inhaled, or absorbed into the body. The applicant shall show in his application that the need for bioassays has been thoroughly considered and should describe the proposed bioassay program in relation to his proposed program for use of radioactive materials. If a commercial bioassay service is to be used, the name and address of the firm should be provided. Two documents which may be used when designing a bioassay program are: U.S. Nuclear Regulatory Commission Regulatory Guide 8.20 entitled, "Applications of Bioassay for I-125 and I-131" and Regulatory Guide 8.32 entitled, "Criteria for Establishing a Tritium Bioassay Program." These documents are available from the Department upon request.

Bioassays may not be substituted for other elements of a safety program such as air monitoring and dispersion control (hoods, glove boxes, etc.) and for well thought out and well executed handling procedures.

Item 13: Facilities and Equipment: Describe in detail the equipment and facilities for each site of use. The proposed equipment and facilities for each operation to be

conducted must be adequate to protect health and minimize danger to life and property. In describing available equipment and facilities, the following types of information should be included, as appropriate:

A. Physical plant, laboratory, or working area facilities. Fume hoods, glove boxes, waste receptacles, special sinks, ventilation and containment systems, effluent filter systems, and all processing, work, and protective clothing change areas shall be described.

B. Containers, devices, protective clothing, auxiliary shielding, general laboratory equipment, air sampling equipment, etc. actually employed in the daily use of material. Special consideration for shielding and containment and provisions to minimize personnel exposure should be described.

C. Storage containers and facilities. Storage containers and facilities should provide both shielding and security for materials. Describe how this will be done.

D. The number, type and length of remote handling devices.

A drawing or sketch should be submitted showing the facilities and equipment and their locations. It should also show the relationship of areas where radioactive material will be handled to unrestricted areas where radioactive materials will not be handled. In those programs where radioactive material may become airborne or may be included in airborne effluents, the drawing or sketch should also include a schematic description of the ventilation system annotated to show air flow rates, differential pressures, filtration and other effluent treatment equipment and air and effluent monitoring instruments. Drawings or sketches should be drawn to a specified scale or dimensions should be included on each drawing or sketch. Each drawing or sketch should be labeled to specify the location of the facilities and equipment depicted with respect to the addresses given in Item 1 of the application.

If respiratory protective equipment will be used to limit the inhalation of airborne radioactive material, the provisions of North Dakota Radiological Health Rules, Section 33-10-04-02, Subsection 3 (pages 4-4 through 4-8) should be followed and appropriate information should be submitted.

Item 14: Radiation Protection Program:

A. Survey Program

Department rules require that surveys be made of external exposure to personnel, air concentrations in the breathing zones of personnel, and effluents from a facility in which radioactive materials are used. A survey may be a physical measurement or a theoretical calculation. Although a theoretical calculation is usually used to demonstrate the lack of a hazard,

from either airborne or external radiation, if can not always be used in lieu of a physical survey.

Except for those cases where sources of radiation and radioactive material are very well known and accurately and precisely controlled, it will usually be necessary that a physical survey be made with appropriate detection and measurement instruments to determine the nature and extent of radiation and radioactive material or, as a minimum, confirm the results of a theoretical determination.

A radiation protection program shall include surveys for radioactive material (contamination) and radiation:

(1) In laboratory areas (contamination on bench tops, handling and storage equipment, clothing, hands, etc.).

(2) During work with radiation or radioactive materials (breathing zone air surveys; general air surveys; personnel exposure measurements, including eyes and extremities; checking shutters and containment, etc.).

(3) Associated with disposal or release of radioactive materials (disposal containers, disposal sites, liquid, gas and solid effluents; filters and filter duct systems, etc.).

The frequency of surveys will depend on the nature of the radioactive materials and their use; however, surveys should be performed prior to the use of radioactive materials in order to establish a baseline and repeated when changes occur in radioactive materials, their containment systems, method of use, etc. Repetitive surveys may also be necessary for the purpose of controlling the location of radioactive materials in the handling system or in the case of the use of sealed sources outside a shielded container.

For operations involving materials in gas, liquid or finely divided forms the survey program must be designed to monitor the adequacy of containment and control of the materials involved. The program shall include air sampling, monitoring of effluents and surveys to evaluate containment of personnel, facilities, and equipment.

The description of an air sampling program should include the area where samples will be taken, the frequency of sampling, and location of the sampler with respect to workers' breathing zones. The type of assays that will be performed to evaluate the samples and the methods to relate results to actual personnel exposures must be described.

The effluent monitoring program for release to unrestricted areas shall encompass all airborne and liquid releases. Theoretical evaluations should be supplemented by stack monitoring, water sampling, or other environmental monitoring appropriate for the planned and potential releases.

For operations involving only sealed sources, a survey program should include evaluation and/or measurement of radiation levels for storage and use configurations. When sources are used in devices having "on" and "off" positions, both positions should be evaluated at the time of installation. Supplemental surveys should be evaluated at the time of installation. Supplemental surveys shall be performed following any changes in operation, shielding, or use. You must specify the types, methods, and frequency of your surveys.

B. Records

Provisions for keeping and reviewing records of surveys; materials inventories; personnel exposures; receipt, use, and disposal of materials; etc. must be described. Persons responsible for keeping and reviewing records shall be identified.

C. Emergency Procedures

Submit written emergency procedures for employees concerning spills, fires, release or loss of material, and/or accidental contamination of personnel. Specifically these procedures should a) specify immediate actions to be taken in order to prevent or limit the contamination of personnel and areas; that is the shutting down of ventilation equipment, evacuation of contaminated and potentially contaminated areas and containment of any spills of radioactive material, b) give the telephone numbers of individuals to be notified in case of emergency and c) instruct personnel in proper entry, decontamination and recovery operations for contaminated facilities (note: only properly trained individuals should attempt decontamination and recovery operations).

D. Sealed Source Leak Test Procedures

Sealed sources containing more than 100 microcuries of a beta or gamma emitter must be leak tested at six-month intervals. Leak testing of alpha particle emitting sources containing more than 10 microcuries of an alpha emitter is required at three-month intervals. If a commercial firm will perform the leak tests, the name, address, and license number of the firm shall be submitted. If the tests are to be performed utilizing a commercial "kit," the name of the kit manufacturer or distributor and the kit model designation must be

given. If the applicant intends to perform his own leak tests (without the use of commercial "kit") the following information shall be submitted:

(1) Qualifications of personnel who will perform the leak test;

(2) Procedures and materials to be used in taking test samples;

(3) The type, manufacturer's name, model number, radiation detection and measurement characteristics of the instrument to be used for assay of test samples;

(4) Instrument calibration procedures, including calibration source characteristics, make and model number; and

(5) The method (including a sample calculation) to be used to convert instrument reading to microcuries of activity.

E. ALARA:

Ensuring that Occupational Radiation Exposures Are As Low As Is Reasonably Achievable (ALARA)

Describe the management policy and organizational structure related to ensuring that occupational radiation exposures are ALARA. Describe the applicable responsibilities and the related activities to be conducted by the individuals having responsibility for radiation protection. Indicate whether, and if so how, the guidance given in Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," will be followed; if it will not be followed, describe the specific alternative approaches to be used.

Please describe special measures that will be undertaken to limit exposure for female employees of child-bearing ages.

The application should contain a commitment by the applicant that all safety-related operations will be conducted in conformance with detailed written procedures. A detailed description of the procedures should be provided.

F. Instructions to Personnel

Written radiation safety instructions must be submitted. These instructions must be the same instructions that will be distributed to persons working with radioactive materials. These instructions should cover, but not necessarily be limited to:

1. The availability, selection and use of laboratory apparel and safety related equipment and devices (e.g., laboratory coats, gloves and remote pipetting devices).

2. Limitations and conditions to be met in handling liquid or uncontained (unencapsulated, dispersible or volatile) radioactive materials and special laboratory equipment to be used in working with these types of materials. For example, these instructions should explain when operations with materials should be confined to a radiochemical fume hood or glove box and should specify the use of appropriate shielding and remote handling equipment when energetic beta emitting or gamma emitting materials are to be used.

3. The performance of radiation survey and monitoring procedures for each area in which radioactive materials are to be used.

4. Safety precautions to be observed in the movement of radioactive materials between buildings, rooms and areas within rooms.

5. Safety requirements for storage of radioactive materials including labeling of containers of radioactive materials and posting and securing areas where radioactive materials are to be used. They should include the storage of contaminated laboratory equipment such as glassware.

6. Requirements for posting of areas in which radioactive materials are used.

7. The availability and use of personnel monitoring devices, including the recording of radiation exposures and the procedures to be followed for the processing of personnel monitoring devices such as thermoluminescent dosimeters and film badges in order to obtain personnel monitoring results.

8. Waste disposal procedures to be followed including limitations on the disposal of liquid or other dispersible waste to the sanitary sewer and procedures for the collection, storage and disposal of other wastes.

9. The maintenance for appropriate records as required by North Dakota Radiological Health Rules Chapters 33-10-03, 33-10-04, and 33-10-10.

10. The requirements for and the method of performing or having appropriate sealed source leak test performed.

11. Good radiation safety practices, including the control of contamination, specification of acceptable removable and fixed contamination levels

for both restricted and nonrestricted areas, prohibition of smoking and the consumption of food or beverages in areas where radioactive materials may be used, and prohibition of the frequent transfer of potentially contaminated equipment between potentially contaminated areas and unrestricted areas.

12. The use of radioactive materials in animals. If radioactive materials will be used in animals, instructions concerning such use should be prepared and submitted with the license application. Such instructions should include: a) specification of the facilities to be used to house the animals, b) instructions to be provided to animal caretakers for handling animals, animal wastes and carcasses, c) instructions to appropriate personnel for cleaning and decontaminating animal cages, and d) method to be used to ensure that animal rooms will be locked or otherwise secured unless attended by authorized users of radioactive materials. A description of animal handling and housing facilities should be included.

Item 15: Waste Disposal: The procedures for disposing of radioactive material waste must be described. Under Department rules, a licensee may dispose of waste in the following ways:

A. Transfer to a person properly licensed to receive such waste. The name of the firm shall be given. (The firm should be contacted in advance to determine any limitations which they may have on acceptance of waste.)

B. Decay and/or release into a sanitary sewer in conformance with Subsection 33-10-04.04.3 of the rules. Depending upon water usage, releases of up to 1 curie per year are permitted.

C. Release into air or water in concentrations conforming with Subsection 33-10-04-02.6 of the rules. Possible exposure to persons off-site limits the amount that may be released.

D. Other methods specifically approved by the Department pursuant to Subsection 33-10-04-04.2 of the rules.

IV. AMENDMENT AND RENEWAL OF LICENSES

Applications for amendment of existing licenses should be filed in the same manner as initial applications or may be filed in letter form. The application should clearly identify the license which is to be amended by license number. The exact nature of the requested changes should be specified and additional supporting information, as necessary, should be provided.

Licenses are normally issued for a period of five years. An application for license renewal filed thirty days or more before expiration assures that the existing license will not expire until the new application has been finally acted upon by the Department.

Renewal applications should be filed using Form SFN 8418 and should contain complete and up-to-date information concerning the applicant's current program. References to previously submitted documents should be clear and specific and specify the document by date and indicate pertinent information by page and paragraph.

Upon submitting an application, the appropriate fee should accompany the application as directed in Chapter 33-10-11. For an amendment to an existing license the fee is $240. The annual fee for a license is $1400, and must be paid by January 1 each year the license is active.

There is no fee associated with license renewal. Fee payments shall be made by check, draft, or money order made payable to the North Dakota Department of Health.